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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH *Plaintiffs,* v. SANDOZ INC., *Defendant.*	Civil Action No. 3:24-641 **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH, (collectively, "Plaintiffs"), by their attorneys, file this Complaint against Defendant Sandoz Inc., ("Sandoz"), and allege the following:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Sandoz of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 7,449,464 ("the '464 patent"); U.S. Patent No. 8,475,842 ("the '842 patent"); U.S. Patent No. 8,859,562 ("the '562 patent"); and U.S. Patent No. 11,633,396 ("the '396 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Sandoz notified Plaintiffs by letter dated December 29, 2023 ("Sandoz's Notice Letter") that it had submitted to FDA ANDA No. 217936 ("Sandoz's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg, ("Sandoz's ANDA Product") prior to the expiration of the Patents-in-Suit.

The Parties

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

4. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized

and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

5. Plaintiff Kudos Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

6. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

7. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

8. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. On information and belief, Sandoz is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

9. On information and belief, Sandoz knows and intends that upon approval of Sandoz's ANDA, Sandoz will manufacture Sandoz's ANDA Product and Sandoz will directly or indirectly market, sell, and distribute Sandoz's ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

10. Plaintiffs incorporate each of the preceding paragraphs 1–9 as if fully set forth herein.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.

§§ 1331, 1338, 2201, and 2202.

12. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sandoz.

13. Sandoz is subject to personal jurisdiction in New Jersey because Sandoz is a corporation with a principal place of business in New Jersey. This Court also has personal jurisdiction over Sandoz because, *inter alia*, on information and belief, Sandoz has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell Sandoz's ANDA Product in the State of New Jersey after approval of ANDA No. 217936.

14. On information and belief, Sandoz is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

15. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA, continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of Sandoz's ANDA.

16. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted Sandoz's ANDA with Paragraph IV

Certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz intends to market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including within the State of New Jersey, that will, as explained below, infringe upon Plaintiffs' rights in the Patents-in-Suit protecting their LYNPARZA® products. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz knows and intends that Sandoz's ANDA Product will be marketed, used, distributed, offered for sale, or sold in the United States, including within the State of New Jersey.

18. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

19. Sandoz has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Amgen Inc. v. Sandoz Inc.*, No. 18-cv-11026, ECF No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, No. 17-cv-10129, ECF No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, No. 17-cv-08825, ECF No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Lab'ys Priv. Ltd.*, No. 17-cv-05302, ECF No. 28 (D.N.J. Nov. 17, 2017). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

20. This Court also has personal jurisdiction over Sandoz at least because, *inter alia*, (a) Sandoz has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product in the United States, including in the State of New Jersey; (b) Sandoz, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Sandoz's ANDA Product in the United

States, including in the State of New Jersey and to residents of this Judicial District, upon approval of Sandoz's ANDA, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in the State of New Jersey; and (c) Sandoz has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if ANDA No. 217936 is approved, Sandoz's ANDA Product charged with infringing the Patents-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

21. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture LYNPARZA® drug products for sale and use throughout the United States, including in this Judicial District. On information and belief, Sandoz filed Sandoz's ANDA with Paragraph IV Certifications, which was purposefully directed to the State of New Jersey, where Sandoz is located. As a result, the consequences of Sandoz's actions were, and will be, suffered in the State of New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in the State of New Jersey. At the time Sandoz sent notice of the Paragraph IV Certifications, it was reasonably foreseeable that Sandoz would be sued within 45 days in this Judicial District, where Sandoz is located. On information and belief, Sandoz's actions will injure Plaintiffs by displacing at least some, if not all, of Plaintiffs' sales of LYNPARZA® drug products in this Judicial District, as well as resulting in price erosion and loss of goodwill with the purchasers

and distributors of LYNPARZA® drug products in this Judicial District.

22. On information and belief, Sandoz has also engaged in substantial, systematic, and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over Sandoz in New Jersey.

Venue

23. Plaintiffs incorporate each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this District under 28 U.S.C. § 1391 because Sandoz resides in this District and a substantial part of the events and injury giving rise to Plaintiffs' claims has and continues to occur in this District.

25. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. On information and belief, among other things, (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including New Jersey; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey

26. Venue is proper in this District as to Sandoz because Sandoz (a) engages in patent litigation concerning Sandoz's ANDA Products in this District, and (b) does not contest that venue is proper in this District.

Factual Background

27. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast,

pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

28. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is olaparib tablets, 100 mg and 150 mg. In Sandoz's Notice Letter, Sandoz states that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that its ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. On information and belief, Sandoz's ANDA Product is a generic version of LYNPARZA®.

29. In Sandoz's Notice Letter, Sandoz stated that it had submitted Paragraph IV Certifications to FDA alleging that the '464, '842, '562, and '396 patents were invalid, unenforceable, and/or not infringed, and that Sandoz is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '464, '842, '562, and '396 patents.

30. The purpose of Sandoz's submission of Sandoz's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

31. In an exchange of correspondence, counsel for Plaintiffs and counsel for Sandoz discussed the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Sandoz's ANDA and any Drug Master File referred to therein, and Sandoz refused to produce samples of Sandoz's ANDA Product and other internal documents and material relevant to infringement.

32. This action is being commenced within 45 days from the date Plaintiffs received Sandoz's Notice Letter.

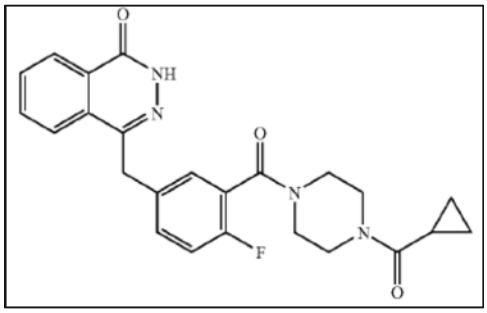
Count I – Infringement of the ’464 Patent Under 35 U.S.C. § 271(e)(2)

33. Plaintiffs incorporate each of the preceding paragraphs 1–32 as if fully set forth herein.

34. On November 11, 2008, the United States Patent and Trademark Office (the “USPTO”) duly and lawfully issued the ’464 patent, entitled “Phthalazinone Derivatives.” A copy of the ’464 patent is attached hereto as Exhibit A.

35. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the ’464 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the ’464 patent.

36. The ’464 patent claims, *inter alia*, a compound of Formula III, shown below, or isomers, salts, or solvates thereof.



37. The compound of Formula III is the compound that is known by the international nonproprietary name olaparib. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

38. LYNPARZA® is covered by Claims 1 and 2 of the ’464 patent, and the ’464 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

39. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s

ANDA Product prior to the expiration of the '464 patent was an act of infringement of the '464 patent under 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, Sandoz's ANDA Product contains olaparib.

41. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe Claims 1 and 2 of the '464 patent, either literally or under the doctrine of equivalents.

42. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe Claims 1 and 2 of the '464 patent.

43. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '464 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

44. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '464 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '464 patent after approval of Sandoz's ANDA.

45. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '464 patent, active inducement of infringement of the '464 patent, and contribution to the infringement by others of the '464 patent.

46. On information and belief, Sandoz has acted with full knowledge of the '464 patent and without a reasonable basis for believing that it would not be liable for infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent.

47. In Sandoz's Notice Letter, Sandoz did not contest infringement of Claims 1 and 2 of the '464 patent on any basis other than the alleged invalidity of those claims.

48. Unless Sandoz is enjoined from infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the '464 Patent

49. Plaintiffs incorporate each of the preceding paragraphs 1–48 as if fully set forth herein.

50. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding validity and/or infringement of the '464 patent.

51. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '464 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '464 patent, and that the claims of the '464 patent are valid.

Count III – Infringement of the '842 Patent Under 35 U.S.C. § 271(e)(2)

52. Plaintiffs incorporate each of the preceding paragraphs 1–51 as if fully set forth herein.

53. On July 2, 2013, the USPTO duly and lawfully issued the '842 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '842 patent is attached hereto as Exhibit B.

54. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the '842 patent.

Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the '842 patent.

55. The '842 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

56. LYNPARZA® is covered by one or more claims of the '842 patent, including at least claims 1 and 7 of the '842 patent, and the '842 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

57. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claims 1 and 7 of the '842 patent, recited above, either literally or under the doctrine of equivalents.

59. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claims 1 and 7 of the '842 patent.

60. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '842 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

61. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing

use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the ’842 patent after approval of Sandoz’s ANDA.

62. The foregoing actions by Sandoz constitute and/or will constitute infringement of the ’842 patent, active inducement of infringement of the ’842 patent, and contribution to the infringement by others of the ’842 patent.

63. On information and belief, Sandoz has acted with full knowledge of the ’842 patent and without a reasonable basis for believing that it would not be liable for infringing the ’842 patent, actively inducing infringement of the ’842 patent, and contributing to the infringement by others of the ’842 patent.

64. Unless Sandoz is enjoined from infringing the ’842 patent, actively inducing infringement of the ’842 patent, and contributing to the infringement by others of the ’842 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count IV – Declaratory Judgment of Infringement of the ’842 Patent

65. Plaintiffs incorporate each of the preceding paragraphs 1–64 as if fully set forth herein.

66. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding validity and/or infringement of the ’842 patent.

67. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the ’842 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’842 patent, and that the claims of the ’842 patent are valid.

Count V – Infringement of the ’396 Patent Under 35 U.S.C. § 271(e)(2)

68. Plaintiffs incorporate each of the preceding paragraphs 1–67 as if fully set forth herein.

69. On April 25, 2023, the USPTO duly and lawfully issued the ’396 patent, entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One.” A copy of the ’396 patent is attached hereto as Exhibit C.

70. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the ’396 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the ’396 patent.

71. The ’396 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

72. LYNPARZA® is covered by one or more claims of the ’396 patent, including at least claim 1 of the ’396 patent, and the ’396 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

73. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’396 patent was an act of infringement of the ’396 patent under 35 U.S.C. § 271(e)(2)(A).

74. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product would infringe at least claim 1 of the ’396 patent, recited above, either literally or under the doctrine of equivalents.

75. On information and belief, the use of Sandoz’s ANDA Product in accordance with

and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '396 patent.

76. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '396 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

77. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '396 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '396 patent after approval of Sandoz's ANDA.

78. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '396 patent, active inducement of infringement of the '396 patent, and contribution to the infringement by others of the '396 patent.

79. On information and belief, Sandoz has acted with full knowledge of the '396 patent and without a reasonable basis for believing that it would not be liable for infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent.

80. Unless Sandoz is enjoined from infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count VI – Declaratory Judgment of Infringement of the '396 Patent

81. Plaintiffs incorporate each of the preceding paragraphs 1–80 as if fully set forth herein.

82. The Court may declare the rights and legal relations of the parties pursuant to 28

U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding validity and/or infringement of the ’396 patent.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the ’396 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’396 patent, and that the claims of the ’396 patent are valid.

Count VII – Infringement of the ’562 Patent Under 35 U.S.C. § 271(e)(2)

84. Plaintiffs incorporate each of the preceding paragraphs 1–83 as if fully set forth herein.

85. On October 14, 2014, the USPTO duly and lawfully issued the ’562 patent, entitled “Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer.” A copy of the ’562 patent is attached hereto as Exhibit D.

86. Plaintiff The University of Sheffield is the assignee of the ’562 patent. Plaintiffs The University of Sheffield, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the ’562 patent.

87. The ’562 patent claims, *inter alia*, a method of treatment of cancer cells defective in homologous recombination (HR).

88. Methods of using LYNPARZA® are covered by Claim 1 of the ’562 patent, and the ’562 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

89. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’562 patent was an act of infringement of the ’562

patent under 35 U.S.C. § 271(e)(2)(A).

90. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe Claim 1 of the '562 patent.

91. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '562 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '562 patent after approval of Sandoz's ANDA.

92. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '562 patent, active inducement of infringement of the '562 patent, and contribution to the infringement by others of the '562 patent.

93. On information and belief, Sandoz has acted with full knowledge of the '562 patent and without a reasonable basis for believing that it would not be liable for the infringing of the'562 patent, and contributing to the infringement by others of the '562 patent.

94. In Sandoz's Notice Letter, Sandoz did not contest infringement of Claim 1 of the '562 patent on any basis other than the alleged invalidity of that claim.

95. Unless Sandoz is enjoined from infringing the '562 patent, actively inducing the infringement of the '562 patent, and contributing to the infringement by others of the '562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count VIII – Declaratory Judgment of the '562 Patent

96. Plaintiffs incorporate each of the preceding paragraphs 1–95 as if fully set forth herein.

97. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one

hand and Sandoz on the other regarding infringement and/or invalidity of the ’562 patent.

98. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the ’562 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’562 patent, and that the claims of the ’562 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Sandoz’s submission to the FDA of Sandoz’s ANDA;
2. A judgment that the Patents-in-Suit are valid and enforceable;
3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Sandoz to make, use, offer for sale, sell, market, distribute, or import Sandoz’s ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity.
4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 371(e)(4)(B) enjoining Sandoz, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Sandoz’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit,

inclusive of any extension(s) and additional period(s) of exclusivity;

5. An order pursuant to this Court's equitable power that the effective date of any final approval of Sandoz's ANDA shall be a date that is not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;
6. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Sandoz's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;
7. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
8. An award of Plaintiffs' costs and expenses in this action; and
9. Such further and other relief as this Court may deem just and proper.

Dated: February 2, 2024

Respectfully submitted,

/s/ Charles H. Chevalier

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